155-159, which correspond to variably-sized sequences resulting from differentially spliced RNA transcripts encoding bovine and human glial growth factor polypeptides.

Summary of the Office Action

Claims 132, 136-138, and 141-143 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 12 of U.S.P.N. 6,204,241 (hereinafter the "'241 patent").

Formalities

The Examiner has requested an amended IDS PTO-1449 listing the publication date for selected PCT applications, US patents and additional documents listed on the previously submitted form PTO-1449. Applicants provide the amended PTO-1449 herewith.

Obviousness-Type Double Patenting Rejection

The Examiner rejects claims 132, 136-138, and 141-143 for obviousness-type double patenting over claim 12 of the '241 patent. The Examiner states that:

> although the conflicting claims are not identical, they are not patentably distinct from each other because amino acids 51 to 422 of SEQ ID NO: 170 of claim 12 of the instant patent contain the amino acid or encoded amino acid sequences being administered for the same purpose of the instant Application.

Applicants respectfully traverse the rejection.

The M.P.E.P. § 804(II)(B)(1) states that "the first question to be asked is - does any claim in the application define an invention that is merely an obvious variation of an invention claimed

in a patent? If the answer is yes, then an 'obviousness-type ' nonstatutory double patenting rejection may be appropriate." Furthermore, the Federal Circuit Court held in *In re Kaplan* (789 F.2d 1574, 229 USPQ 678 (Fed. Cir. 1986)) that:

> to establish "obviousness-type" double patenting as to an attempt to obtain a patent on a variation of an invention claimed in a prior patent, there must be some clear evidence to establish why the variation would have been obvious. The evidence must relate to material that qualifies as "prior art."

The Examiner, by stating that SEQ ID NO: 170 of claim 12 of the '241 patent "contain[s] the amino acid or encoded amino acid sequences being administered," suggests that the use of the polypeptides of the instant invention would be an obvious variation in a method for inducing acetycholine receptor synthesis in a cell, however, the Examiner has failed to provide any prior art evidence to support this assertion, as required, *Supra*. Applicants point out that SEQ ID NOs: 152, and 155-159, which represent bovine and human glial growth factor polypeptides produced from variably-sized, differentially spliced RNA transcripts (see page 34, lines 2-22, of the specification) and are recited in claims 132, 138, and 141 of the instant invention, contain sequence information that is not found in SEQ ID NO: 170. The court held in *In re Vogel* (422 F.2d 438, 164 USPQ 619 (CCPA 1970) that "if the rejected claim defines more than an obvious variation, it is patentably distinct." These polypeptide fragments are not provided by SEQ ID NO: 170 and one skilled in the art would not be directed to the use of these polypeptides based on the sequence disclosed in SEQ ID NO: 170, therefore, these polypeptides do not constitute an obvious variation and are patentably distinct.

Applicants also argue that the Examiner has not met the burden of showing that SEQ ID NO: 151, which corresponds to amino acids 362-411, of bovine GGF2, and SEQ ID NOs: 154,

and 188-190, which correspond to amino acids 358-422, amino acids 350-411, amino acids 350-422, amino acids 362-411, respectively of human GGF2, and which are recited in claims 132, 138, and 141 of the instant application, constitute an obvious variation based on claim 12 of the '241 patent. The Examiner states that:

> [because] amino acids 51-422 of SEQ ID NO: 170 contain the "active portion" or the "EGF-like" domain of SEQ ID NO: 170,...it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the "active portion" of the polypeptide for therapeutic purposes while minimizing the size of the polypeptide for better tissue penetration and pharmacokinetics in general.

Applicants point out that claim 12 of the '241 patent requires that the polypeptide contain amino acids 51-422. Claim 12 of the '241 patent lacks any suggest that would direct one skilled in the art to use a shorter polypeptide, especially one lacking over 80% of the sequence information contained within SEQ ID NO: 170, in the instant method. Therefore, one skilled in the art would not be directed, based solely on claim 12 of the '241 patent, to use the specific polypeptides claimed in the instant invention. Even if it would be obvious to one skilled in the art to test smaller polypeptides for activity, the court held in *Ecolochem Inc. v. Southern California Edison Co.* (227 F.3d 1361, 56 USPQ2d 1065 (Fed. Cir. 2000) that "'obvious to try' is not the standard." Therefore, based on the foregoing remarks, Applicants respectfully request withdrawal of the rejection of claims 132, 136-138, and 141-143 for obviousness-type double patenting.

CONCLUSIONS

Applicants submit that the claims are now in condition for allowance, and such action is respectfully requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: January 28, 2002

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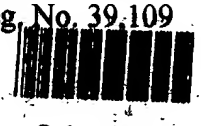

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